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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,788

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Gerd Hummel

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WASHINGTON, DC 20005

EXAMINER

NIEBAUER, RONALD T

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,788	<b>Applicant(s)</b> HUMMEL ET AL.	
	<b>Examiner</b> RONALD T. NIEBAUER	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2008 and 20 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 125-140 is/are pending in the application.
- 4a) Of the above claim(s) 127-140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 125-126 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants amendments, arguments, and affidavit filed 4/29/08 and summary of the interview filed 5/20/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

#### ***Election/Restrictions***

Previously, Applicant elected with traverse Group II claims 85-101 and the species of compound number 352 of claim 124 and the species of chemical bond in the reply filed on 8/27/07.

Claims 1-124 have been cancelled. Claims 125-140 have been added as new claims.

Claims 125,126 read on the elected invention and species.

Newly submitted claim 127-140 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions of claims 125-126 (drawn to compounds/compositions) and the invention of claims 127-140 (drawn to methods of treating) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case methods of treating psoriasis, for example, can be carried out with a materially different product. Further, the product can be used in a materially different process such as in the production of antibodies.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 127-140 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 125-126 are under consideration.

### ***Claim Rejections - 35 USC § 103***

The below rejections use the same references as in the previous office action. Due to the claim amendments the rejections have been updated to relate to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 125-126** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. (US 5,387,671 as cited previously).

Kawai teach C5a receptor modulating compounds (claim 1 and column 1-2). Kawai teach that the compounds are ligands for the anaphylatoxin receptor and are useful in the treatment of inflammatory disease states (abstract). Kawai teach in claim 1 a genus of compounds that are anaphylotoxin activity modulating compounds. Kawai teach many compounds of the genus of claim 1 in examples 1-178 and claims 10-14. Kawai specifically teach the compound (N-Methyl)Phenylalanyl-Lysyl-Prolyl-[(2R)-2-amino-3-cyclohexylpropanoyl]-Phenylalanyl-D-(N-

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Methyl)-Phenylalanyl-OH (example 171 (column 52)). Kawai teach the compounds in compositions comprising a pharmaceutical carrier (column 10 lines 27-30, column 22 last paragraph) as recited in instant claim 126.

Kawai does not teach an embodiment or specific example of the elected species (i.e. the compound recited in claim 125).

In claim 1, Kawai teach a broad genus of compounds of the formula A-B-D-E-G-J-L-M-Q (shown schematically in columns 9-12). Many compounds, including the elected species Hoo-Phe-Orn-Pro-hle-Pff-Phe-NH<sub>2</sub> are rendered obvious from the genus taught by Kawai. Kawai teach that the compounds are ligands for the anaphylatoxin receptor and are useful in the treatment of inflammatory disease states (abstract). Kawai teach in claim 1 a genus of compounds that are anaphylotoxin activity modulating compounds. As such, one would be motivated to make the compounds of the genus of claim 1 of Kawai.

In comparing the current invention to that of Kawai a comparison will be made between each of the residues of claim 125 of the current invention (which will be identified as X1-X2-X3-X4-X5-X6-X7-X8 where X1 is Hoo, X2 is Phe, etc.). Instead of identifying each of R1-R300+ of Kawai, the examples of Kawai will be used to illustrate the genus of compounds.

From example 171 of Kawai discussed above, X2 is Phe, X4 is Pro, X7 is Phe. Hence the corresponding residues of the elected species are clearly within the genus taught by Kawai. Further, Kawai teach example 74 with Orn at X3, and example 5 with leucine at position X5 (if Leu is a member of the genus then Hle is clearly within the genus as well). Kawai teach that the terminal radical (R25-R26-R27 of claim 1) can be NR109 with R109 being hydrogen, R26 being absent and R27 being hydrogen resulting in X8 of the current invention. Since aryl (R1) is

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defined to be substituted or unsubstituted aromatic, Hoo (substituted pyrimidine) is possible at X1 and fluorenyl is possible at position X6.

In summary:

Elected species	Hoo-	Phe-	Orn-	Pro-	hle-	Pff-	Phe	-NH2
Kawai example 171	xxx	Phe	xxx	Pro	xxx	Phe	m-Phe	
Kawai example 74	xxx	Phe	m-Orn	Pro	xxx	xxx	xxx	
Kawai example 5	xxx	Phe	xxx	xxx	Leu	xxx	xxx	
Kawai claim 1	A	BD	E	G	J	L	M	Q (where for example, B and D together can represent a particular group).

Taken together the elected species falls within the genus of claim 1 of Kawai. Therefore the elected species is a species of the genus described in Kawai. As such the limitations of claim 125 of the instant invention are met. Kawai teach the compounds in compositions comprising a pharmaceutical carrier (column 10 lines 27-30, column 22 last paragraph) thus meeting the limitations recited in instant claim 126.

In the instant case, one would be motivated to derive the compounds discussed in Kawai, for example those discussed in claim 1, because Kawai teach that the compounds are ligands for the anaphylatoxin receptor and are useful in the treatment of inflammatory disease states (abstract). Further, it is noted that Section 2121 I of the MPEP states that prior art is presumed to be enabling. In the instant case, the compounds of Kawai are part of the claims of an issued US patent. As such, the claims are enabled and meet all the requirements of 112 1st paragraph for example.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Response to Arguments 103***

Since the claims have been amended, a new rejection adapted to the claims is recited above using the same references as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants argue that Kawai teach a polar and charged arginine is required to be present to achieve significant antagonistic activity and that Kawai teach numerous examples with a terminal arginine. Applicants argue that had Kawai recognized the high affinity compounds Kawai would have made and tested more of them. Applicants argue that example 170 of Kawai has an activity that is insufficient for use as a drug.

Applicants have submitted a Rule 132 declaration. Applicant has performed tests comparing the compounds of example 171 of Kawai and the compound of claim 125 in a specific type of assay. Applicants report that the specific compound of Kawai is not as active as the compound of the instant invention. Applicants argue that one of skill in the art would not be motivated to derive compounds with a phenylalanine substituent as in the present claims.

Applicant's arguments filed 4/29/08 have been fully considered but they are not persuasive.

Although applicants assert that Kawai teach a polar and charged arginine to be present to achieve significant antagonistic activity, it is noted that the genus of claim 1 is drawn to more than just arginine at the terminal amino acid position. For example, in claim 1 of Kawai the compound is X1-X2-X3-X4-X5-X6-X7-X8 as discussed above. Kawai teach that the terminal radical (i.e. X8) (R25-R26-R27 of claim 1) can be NR109 with R109 being hydrogen, R26 being absent and R27 being hydrogen resulting in X8 of the current invention. Kawai teach that M, the terminal amino acid, can be R31 for example, which can be Phe. Kawai specifically teach the compound (N-Methyl)Phenylalanyl-Lysyl-Prolyl-[(2R)-2-amino-3-cyclohexylpropanoyl]-Phenylalanyl-D-(N-Methyl)-Phenylalanyl-OH (example 171 (column 52)) in which the terminal residue is not arginine. Therefore, the genus of compounds of Kawai and the specific examples are not limited to compounds with a terminal arginine. Further, although applicants argue that had Kawai recognized the high affinity compounds Kawai would have made and tested more of them, it is noted that Kawai does teach a range of compounds in claim 1 for example.

Although applicants argue that one of the examples of Kawai does not meet their definition of a drug, Kawai teach that the compounds are ligands for the anaphylatoxin receptor



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and are useful in the treatment of inflammatory disease states (abstract) and as such one would be motivated to make such compounds. It is noted that in the instant case, the claims are drawn to compounds. A new activity or use of an old compound is not patentable (see MPEP section 2112.02 for example).

The affidavit under 37 CFR 1.132 filed 4/29/08 is insufficient to overcome the rejection of claims 125-126 based upon Kawai et al. (US 5,387,671 as cited previously) applied under 35 U.S.C. 103(a). It is noted that applicant has made comparisons between one compound of Kawai with the one compound of the instant invention. However, Kawai, in claim 1 for example, teach a genus of compounds. Kawai teach that the compounds are ligands for the anaphylatoxin receptor and are useful in the treatment of inflammatory disease states (abstract). Kawai teach in claim 1 a genus of compounds that are anaphylotoxin activity modulating compounds. As such, one would be motivated to derive the compounds of claim 1. As discussed in detail above, the genus of compounds of claim 1 of Kawai are not limited to a terminal arginine. Kawai teach that M, the terminal amino acid, can be R31 for example, which can be Phe. As such, there are many compounds in the genus of Kawai with something other than a terminal arginine. Although applicants argue that the activity is low for one compound, Kawai teach that the compounds are ligands for the anaphylatoxin receptor and are useful in the treatment of inflammatory disease states (abstract). A new activity or use of an old compound is not patentable (see MPEP section 2112.02 for example). Further, it is noted that Section 2121 I of the MPEP states that prior art is presumed to be enabling. In the instant case, the compounds of Kawai are part of the claims of an issued US patent. As such, the claims are enabled and meet all the requirements of 112 1st paragraph for example. MPEP section 716 highlights the use of 132 declarations. In the instant

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case (see MPEP section 716.02(b)) applicant has not established that any results are unexpected and significant. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

### ***Double Patenting***

The previous office action recited a statutory type double patenting rejection. Due to the claim amendments a new rejection is cited below.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 125-126** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44-45 of copending Application No. 11/814,050 (‘050). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 44 of copending Application No. 11/814,050 recites the identical species as claim 125 of the current application: Hoo-Phe-Orn-hle-Pff-Phe-NH<sub>2</sub> (compound 352). Further, Claim 45 of copending Application No. 11/814,050 recites pharmaceutically acceptable carriers as in instant claim 126.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 125-126 are directed to an invention not patentably distinct from claims 44-45 of commonly assigned 11/814,050 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/814,050, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

***Response to Arguments Double Patenting***

Since the claims have been amended, a new rejection adapted to the claims is recited above. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

Applicants request that the rejection be held in abeyance until one of the cases issues.

Applicant's arguments filed 4/29/08 have been fully considered but they are not persuasive.

Section 804 I B1 of the MPEP states that a provisional obviousness-type double patenting rejection can be withdrawn if the obviousness-type double patenting rejection is the only rejection remaining in the earlier filed application. In the instant case, there are other outstanding rejections. Thus, the obviousness-type double patenting rejection should not be withdrawn.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/  
Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654